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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0025]

Medical Devices: Draft Guidance for Industry and FDA; The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Draft Guidance for Industry and FDA." The draft guidance document is intended to assist facilities and their personnel in meeting the MQSA final regulations. This document deals with requirements related to testing of the automatic exposure control (AEC) component of mammography units.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled "The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Draft Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for

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Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Charles Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance serves to clarify and update previously issued guidance on testing the AEC component of mammography units. Due to the use of increasingly sophisticated mammography units, previously issued guidance on this matter does not adequately address the issue. This draft guidance was developed with input from the National Mammography Quality Assurance Advisory Committee during a meeting held on August 26, 2002. Once finalized, this guidance will supersede the AEC guidance that currently appears in the July 18, 2002, version of the MQSA Policy Guidance Help System (http://www.fda.gov/cdrh/mammography/robohelp/START.HTM).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on testing of the AEC component of mammography

units. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

II. Comments

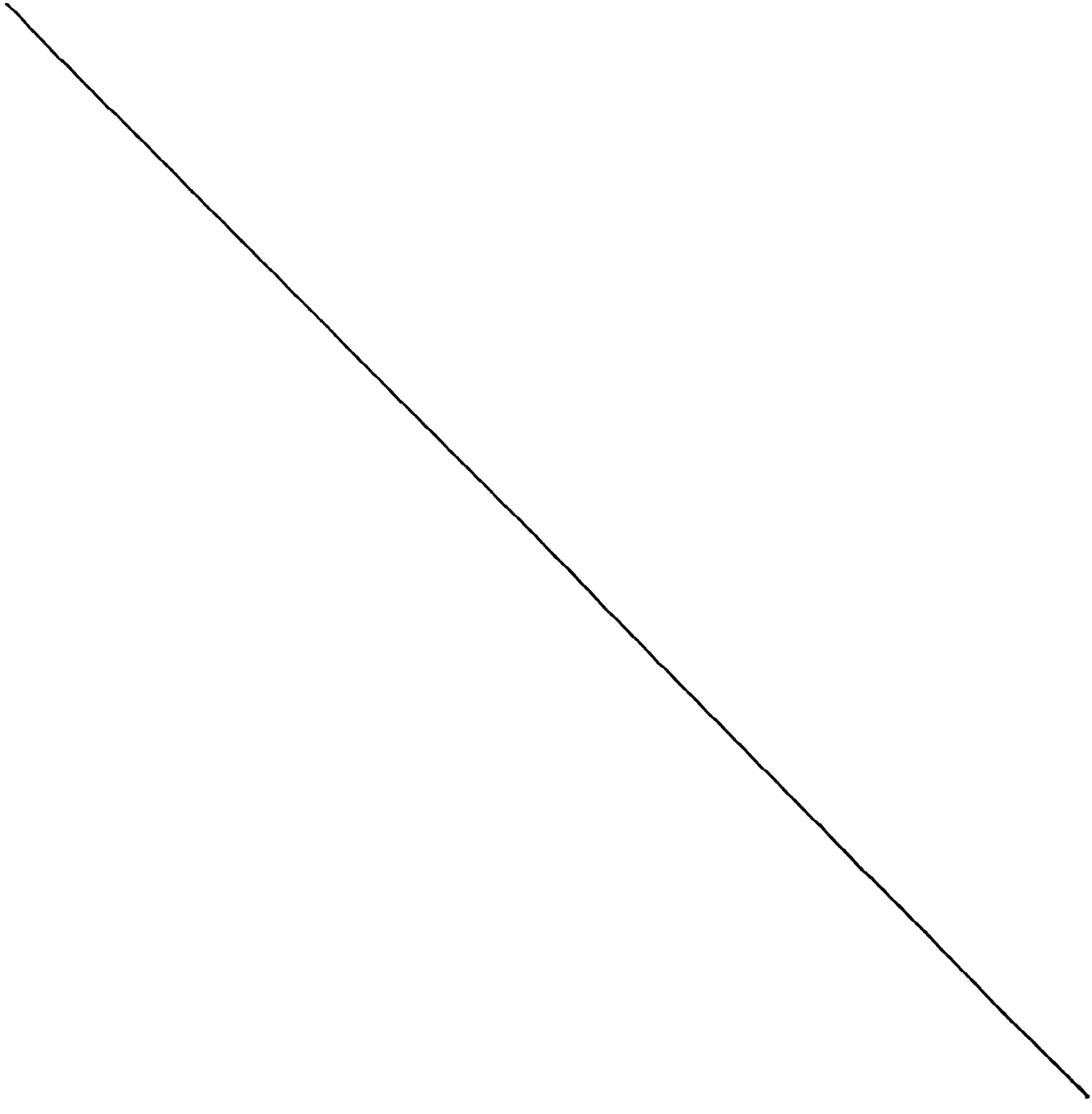
Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments. Two hard copies of any mailed comments are to be submitted, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

To receive "The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Draft Guidance for Industry and FDA" by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1435) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular

basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at http://www.fda.gov/cdrh. A search capability for all CDRH guidance documents is available at http://www.fda.gov/cdrh/guidance.html.



Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets.

Dated: 2/3/03
February 3, 2003.

Linda S. Kahan

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